



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. 30-4675; NRC-2017-0221]

**Department of Health and Human Services, Food and Drug Administration,
Winchester Engineering and Analytical Center**

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; opportunity to provide comments, request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received a license amendment application from the Department of Health and Human Services, Food and Drug Administration (FDA) for the Winchester Engineering and Analytical Center located in Winchester, MA. The license authorizes the use of radioactive byproduct material for research and development. The licensee is requesting a partial site release for construction of a new 3-story building directly behind the existing main lab building.

DATES: Submit comments by **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. A request for a hearing or petition for leave to intervene must be filed by **[INSERT DATE 60 DAYS FROM DATE OF PUBLICATION]**.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0221. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: OWFN-2-A13, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Stephen Hammann, Division of Nuclear Materials Safety, Region I, U.S. Nuclear Regulatory Commission, 2100 Renaissance Boulevard, Suite 100, King of Prussia, Pennsylvania 19406; telephone: 610-337-5399; fax number: 610-337-5269; e-mail: Stephen.Hammann@nrc.gov

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2017-0221 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information

related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and

search for Docket ID NRC-2017-0221.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The Decommissioning Plan is available in ADAMS under Accession No. ML17215A952.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2017-0221 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for

submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction.

The NRC has received, by letters dated November 25, 2016, (ADAMS Accession No. ML16347A523) and July 21, 2017, (ADAMS Accession Nos. ML17215A952 and ML17215A953) an application to amend Materials License No. 20-08361-01 and a decommissioning plan, respectively. The amendment provides for a partial site release. The decommissioning plan includes the radiological survey and subsequent excavation, decontamination, and proper disposal of licensed radioactive material identified within a designated area of the site. Specifically, the approval of the decommissioning plan would allow FDA to begin remediation activities in the specified area of the Winchester Engineering and Analytical Center to confirm that the specified area would meet the requirements for release for unrestricted use as specified in section 14.02 of title 10 of the *Code of Federal Regulations* (10 CFR). Materials License No. 20-08361-01 currently authorizes use of radioactive material for research and development as defined in 10 CFR 30.4 and 10 CFR 70.4.

An NRC administrative completeness review found the application acceptable for a technical review (ADAMS Accession No. ML17215A953). Prior to approving the

proposed action, the NRC will need to make the findings required by the Atomic Energy Act of 1954 as amended (the Act), and the NRC's regulations. The NRC's findings will be documented in a safety evaluation report and an environmental assessment. The environmental assessment will be the subject of a subsequent notice in the *Federal Register*.

III. Notice and Solicitation of Comments.

In accordance with 10 CFR 20.1405, the Commission is providing notice and soliciting comments from local and State governments in the vicinity of the site and any Federally-recognized Indian Tribe that could be affected by the decommissioning. This notice and solicitation of comments is published pursuant to § 20.1405, which provides for publication in the *Federal Register* and in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site. Comments should be provided within 30 days of the date of this notice.

IV. Opportunity to Request a Hearing and Petition for Leave to Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10

CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) the name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute

exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions set forth in this section.

Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

V. Electronic Submissions (E-Filing).

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic

Submissions to the NRC and on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a

transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike,

Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Dated at King of Prussia, Pennsylvania, this 17th day of November 2017.

For the Nuclear Regulatory Commission.

Raymond J. Powell, Chief,
Decommissioning, ISFSI, and Reactor Health
Physics Branch,
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